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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/798,780

03/12/2004

Doris Hubler

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EXAMINER

HUI, SAN MING R

ART UNIT

PAPER NUMBER

1617

MAIL DATE

DELIVERY MODE

07/03/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/798,780	Applicant(s) HUBLER ET AL.	
	Examiner San-ming Hui	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,5,6,21-25 and 29-56 is/are pending in the application.
4a) Of the above claim(s) 38-56 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,3,5,6,21-25 and 29-37 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>12/11/07, 5/27/08</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Applicant's amendments filed February 15, 2008 have been entered. Claims 2, 4, 7-20, and 26-28 have been cancelled. Claims 29-56 have been added.

Newly submitted claims 38-56 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the claims are directed to a method of male contraception. Such method is patentably distinct from the composition as claimed since the method of male contraception can be practiced with a materially different product such as condom.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 38-56 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 1, 3, 5-6, 21-25, and 29-37 have been examined to the extent they read on the elected invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3, 5-6, 21-25, and 29-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO95/12383 ('383) in view of Riffkin et al., Journal of Pharmaceutical Sciences, 1964, vol. 53, no. 8, p. 891-895), both references are of record.

'383 teaches an injectable solution comprising testosterone undecanoate, benzyl benzoate and a vegetable oil (See the abstract, also claims 1 and 2).

'383 does not expressly teach castor oil as one of the vegetable oil vehicle in the testosterone undecanoate injectable composition. '383 does not expressly teach the herein claimed ratio between castor oil and benzyl benzoate. '383 does not expressly teach the dose of testosterone undecanoate in the composition.

Riffkin et al. teaches that vehicle comprising castor oil and benzyl benzoate in a ratio of 1:1 or 65:35 as useful in delivering steroidal compounds for parenteral composition (See page 893 – 894, Table IV). Riffkin et al. also teaches that by adding benzyl benzoate into the composition would lower the viscosity of the composition and make the parenteral composition easy to be injected (See page 894, col. 1, first paragraph).

It would have been obvious to one of ordinary skill in the art at the time of invention to incorporate castor oil and benzyl benzoate, in the ratio herein claimed and dosage herein claimed, in the parenteral composition containing testosterone undecanoate.

One of ordinary skill in the art would have been motivated to incorporate castor oil and benzyl benzoate, in the ratio herein claimed and the dosage herein claimed, in

the parenteral composition containing testosterone undecanoate since castor oil, among other vegetable oils, is known to be suitable vehicles for injectable composition for steroids. Therefore, by adding benzyl benzoate and castor oil as a vehicle to the injectable testosterone undecanoate composition, one of ordinary skill in the art would be reasonably expected to be successfully formulate a parenteral intramuscular composition for testosterone undecanoate. Employing benzyl benzoate in a parenteral composition is reasonably expected to lower the viscosity and make the composition easier to be injected. Furthermore, optimization of result effect parameters (e.g., dosage of the active and range amount of the solvent employed) is obvious as being within the skill of the artisan.

Response to Arguments

Applicant's arguments filed February 15, 2008 averring the cited prior art's failure to teach or suggest the weight ratio of castor oil and benzyl benzoate have been fully considered but they are not persuasive. Absent evidence to the contrary, the optimization of the amount of excipients is considered obvious as being within the purview of the skilled artisan.

Applicant's arguments and the declaration by Dr. Fricke filed February 15, 2008 averring the presence of unexpected benefits have been considered, but are found not persuasive to obviate the outstanding rejection under 35 USC 103(a). It is applicant's burden to demonstrate unexpected results over the prior art. See MPEP 716.02, also 716.02 (a) - (g). Furthermore, the unexpected results should be demonstrated with evidence that the differences in results are in fact unexpected and unobvious and of

both statistical and practical significance. *Ex parte Gelles*, 22 USPQ2d 1318, 1319 (Bd. Pat. App. & Inter. 1992). Moreover, evidence as to any unexpected benefits must be "clear and convincing" *In re Lohr*, 137 USPQ 548 (CCPA 1963), and be of a scope reasonably commensurate with the scope of the subject matter claimed, *In re Linder*, 173 USPQ 356 (CCPA 1972). In the instant case, the showing in the declaration demonstrates only one concentration of castor oil in which makes the testosterone undeconoate composition become unexpectedly stable. However, such showings do not reasonably commensurate with the scope of the subject matter claimed. Therefore, the claims are considered properly rejected under 35 USC 103(a).

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (571) 272-0626. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

San-ming Hui
Primary Examiner
Art Unit 1617

/San-ming Hui/
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